REMARKS

I. REJECTIONS UNDER 35 U.S.C. 112, SECOND PARAGRAPH

A. Claim Rejections

The Office Action rejects claims 1 and 11 under 35 U.S.C. 112, second paragraph, stating that it is "not clear what a safe and effective amount is." Applicants respectfully refer Examiner to the Interview Summary of the interview conducted on July 8, 2003, in which Examiner agreed to withdraw this rejection.

The Office Action rejects claims 3 and 12 under 35 U.S.C. 112, second paragraph, stating that "the phrase 'wax like' renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by 'wax like'), thereby rendering the scope of the claim(s) unascertainable." The Office Action further rejects claims 3 and 12 on the basis that "the phrase 'such as' renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention." As noted in the Interview Summary, Applicants have amended claims 3 and 12 to exclude the phrases "wax-like" and "such as" from these claims. Applicants respectfully submit that these rejections are thus overcome.

The Office Action rejects claims 3 and 12 under 35 U.S.C. 112, second paragraph, stating that by reciting "cellulose derivatives" and then further listing various cellulose-containing compounds, the intent of the applicants is unclear whether the cellulose derivatives include the cellulose derivatives listed in the claims. As noted in the Interview Summary, applicants have amended claims 3 and 12 to exclude the phrase "cellulose derivatives." Applicants respectfully submit that this rejection is overcome.

Finally, the Office Action rejects claims 23 and 24 under 35 U.S.C. § 112, second paragraph, asserting that the limitation "the desired site" has insufficient antecedent basis. The Office Action further rejects Claims 23 and 24 under 35 U.S.C. § 112, second paragraph, as being vague and indefinite "because, according to the claims, by orally administering the composition of claim 1 or 11, 'the desired site of a therapeutically active agent in the gastrointestinal tract' is maintained and it is not clear how the desired site of delivery is maintained and it is unclear what is being claimed." Applicants respectfully traverse these rejections and refer Examiner to amended claims 23 and 24.

Claim 23 has been amended to read as follows:

> A method of consistent and reliable delivery and release of a therapeutically active agent to the desired region of delivery by orally administering the composition of claim 1.

Claim 24 has been similarly amended, but refers to "the composition of claim 11" rather than claim 1. Antecedent basis for this amendment is at page 2, lines 8-11 of the specification:

> None of the above prior art references, however, discusses the problem or possibility of coating fractures that may occur during processing, manufacturing, or packaging of the oral unit dosage form. Coating fractures may cause unreliable or inconsistent delivery or release of the therapeutic agent *to the desired region* of the gastrointestinal tract. (Emphasis added).

Applicants submit that the amended claim clarifies that, rather than a method of maintaining a desired site, the method is one of delivering and releasing a therapeutically active agent to the desired region. This delivery and release is achieved by administering the therapeutically active agent in a solid unit dosage form of the present invention claimed herein. This method reflects an embodiment of the invention wherein the function of the outer coating layer is to prevent or minimize fractures of the inner coating layer during formulation processing, manufacturing, and packaging, and the function of the inner coating layer is to maintain the desired point of release of the therapeutic active agent in the gastrointestinal tract (p. 7, lines 22-25).

In light of the foregoing amendments, Applicants respectfully submit that the amended claims now possess the requisite degree of clarity and definiteness, and that Examiner's rejections have been overcome.

B. Claim Objections

The Office Action objects to claims 8, 10, 19 and 21 because these claims recite 5-ASA without an initial definition of 5-ASA. Applicants have amended these claims to refer to 5-aminosalicylic acid, rather than 5-ASA. The antecedent basis for this amendment is found, *inter alia*, on page 4, line 23 of the specification, which includes 5-aminosalicylic acid among the examples of therapeutically active agents. Applicants submit that in light of these amendments, the Examiner's rejection is overcome.

II. REJECTIONS UNDER 35 U.S.C. 102

The Office Action rejects claims 1-4, 8-14 and 19-22 under 35 U.S.C.102(b) as being anticipated by Iarmartino et al. (US 5,171,580). The Office Action further rejects claims 1-4, 8, 9, 11-14, 19, 20 and 22 under 35 U.S.C. 102(b) as being anticipated by Rommelmayer (WO 98/27967). Applicants respectfully traverse these rejections.

A. Anticipation by Iamartino et al. ('580).

According to M.P.E.P. § 2131, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Iamartino et al. ('580) discloses a pharmaceutical preparation comprised of a core, which contains the therapeutically active ingredient, surrounded by an inner layer, an intermediate layer and an outer layer (column 3, lines 18-30). Examiner alleges that the "comprising" language does not exclude the presence of the intermediate layer in Iarmartino ('580).

Instant claims 1 and 11 have been amended to include language that explicitly excludes the intermediate layer of Iamartino. Part (c) of claims 1 and 11 reads, in the relevant portion, as: "an outer coating layer, ***applied to the inner coating layer***, comprising an enteric polymer or film coating material;" (Emphasis added).

Applicants submit that antecedent basis for this amendment is found, *inter alia*, in the examples. Example 4 provides for the outer coating layer to be applied to the inner coating layer by stating that "[a]n inner layer ... is applied to the core tablets" wherein subsequently "[a]n outer coating layer is applied ***to the core tablet and inner coating layer***" (p. 13, line 21; p. 14, line 2, emphasis added). Similarly, examples 1, 2 and 3 state that "[a]n outer coating is either applied ***immediately following*** the application of the inner coating or once the inner coating has cured" (page 12, lines 3-4 and 18-19; page 13, lines 6-7, emphasis added). Here, the use of the term "immediately following" describes a temporal relationship that precludes the application of the intermediate layer of Iamartino. Example 6 states: "Applied to the core tablets described in Example 4 is an inner layer of an aqueous EUDRAGIT® L 30 D-55 coating ... An outer coating layer is ***then*** applied ... " (p. 14, lines 10- 17, emphasis added). Here, the word "then" is used in the same temporal sense as the term "immediately" in examples 1-3. These examples, therefore, provide basis for a claim amendment that excludes the intermediate layer of Iarmartino ('580).

Accordingly, the amended claims 1 and 11 clearly exclude the intermediate layer of Iamartino ('580) and require the outer coating layer to be applied to the inner coating layer.

Because the ('580) patent no longer teaches each and every element of the present invention in view of the instant amendment, Applicants submit that this rejection has been overcome.

B. Anticipation by Rommelmayer ('967)

Rommelmayer ('967) discloses a tablet comprising a core, which contains the biologically active ingredient, an enteric coating and an outer coating consisting of one or more polymer(s) (page 1, lines 6 – 17). Notably, the enteric inner coating most preferred in Rommelmayer is Eudragit®L30D (p. 11, line 8).

Eudragit®L30D is defined, per Applicant's specification in the context of describing specific examples of the outer coating layer, as an anionic copolymer derived from methacrylic acid and **ethyl acrylate** (p. 8, lines 4-5, emphasis added). In constrast, Applicants' invention claims an inner coating layer selected from the group consisting of poly(methacrylic acid, **methyl** methacrylate) 1:2, poly(methacrylic acid, **methyl methacrylate**) 1:1, and mixtures thereof (emphasis added).

In one embodiment of the invention, the inner coating is Eudragit®S, which is defined as an anionic copolymer derived from methyacrylic acid and **methyl methacrylate**, with a ratio of free carboxyl groups to the ester groups of approximately 1:2 and a mean molecular weight of approximately 135,000 (p. 5, lines 13-16). In another embodiment of the invention, the inner coating is Eudragit®L, which is defined as an anionic copolymer derived from methacrylic acid and **methyl methacrylate**, with a ratio of free carboxyl groups to the ester groups of approximately 1:1 and a mean molecular weight of approximately 135,000 (p. 8, lines 1-3).

Applicants submit that because Rommelmayer ('967) fails to teach, *inter alia*, the inner coating of the present invention, the rejection is traversed.

III. REJECTIONS UNDER 35 U.S.C. 103

The Office Action rejects claim 15 under 35 U.S.C. 103(a) as being unpatentable over Rommelmayer ('967). The Office Action further rejects claims 5-7 and 16-18 under 35 U.S.C. 103(a) as being unpatentable over Iamartino ('580). Claims 23 and 24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious, over both Rommelmayer ('967) and Iamartino ('580). Applicants respectfully traverse these rejections.

According to M.P.E.P. § 2142, three criteria all must be met to establish a prima facie case of obviousness. First, the combined prior art references must teach or suggest all of the

claim limitations. Second, there must be some suggestion or motivation to combine the references' teachings. Finally, there must be a reasonable expectation of success. Applicants assert that the cited art fails to meet any of these criteria.

In regard to claims 15, 5-7 and 16-18, in light of the previous discussion, it is clear that the cited art fails to teach or suggest all of the claim limitations. The present invention specifically excludes the presence of an intermediate layer as described in Iamartino ('580), and also excludes the use of Eudragrit®L30D in the inner coating layer, as described in Rommelmayer ('967). Therefore, neither a single reference nor a combination of the references teach or suggest all of the claim limitations.

Moreover, Applicants submit that cited references fail to discuss the problem or possibility of coating fractures that may occur during processing, manufacturing, or packaging of the oral unit dosage form, and that coating fractures may cause unreliable or inconsistent delivery or release of the therapeutic agent to the desired region of the gastrointestinal tract.

In view of the foregoing, Applicants submit the references further fail to provide the requisite suggestion or motivation and reasonable expectation of success. As such, Applicants respectfully assert that the rejections under 35 U.S.C. 102(b) and 103(a) have been overcome/traversed.

CONCLUSION

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejections under 35 U.S.C. 112, 102 and 103. Early and favorable action in the case is respectfully requested.

Applicants have made an earnest effort to place their application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, Applicants respectfully request reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1-24.

Respectfully submitted,
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